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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,175

Applicant(s)

GLORIOSO ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 16,18,24 and 29-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15, 17, 19-23, 25-28 and 45-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-48 are pending.
2. Applicant's election of the invention of group I, claims 1-28 is acknowledged. In response to the restriction requirement, applicants amended claims. In view of the applicants' amendments, elected invention of claims 1-28 and newly presented claims 45-48 are subjected to further restriction as discussed below.
3. Claims 16, 18, 24 and 29-44 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.
4. Claims 1-15, 17, 19-23, 25-28 and 45-48 are under consideration.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 15, 17, 19-23, 25, 26 and 47, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing BMP in the host, classified in class 424, subclass 93.2.
 - II. Claims 1-5, 8, 15, 17, 19-23, 25, 26 and 46, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing IL-10 in the host, classified in class 424, subclass 93.2.
 - III. Claims 1-5, 9, 15, 17, 19-23, 25 and 26, drawn to a method of treating a connective disorder in a mammalian host by transplanting a

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connective tissue cell expressing growth hormone in the host, classified in class 424, subclass 93.2.

- IV. Claims 1-5, 10, 11, 15, 17, 19-23, 25 and 26, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing IGF in the host, classified in class 424, subclass 93.2.
- V. Claims 1, 2, 12, 15, 17, 19, 20, 22, 23, 25, 26 and 45, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing IL-1 receptor in the host, classified in class 424, subclass 93.2.
- VI. Claims 1, 2, 13, 15, 17, 19, 20, 22, 23, 25 and 26, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing TNF-alpha receptor in the host, classified in class 424, subclass 93.2.
- VII. Claims 1, 2, 14, 15, 17, 19, 20, 22, 23, 25 and 26, drawn to a method of treating a connective disorder in a mammalian host by transplanting a connective tissue cell expressing proteinase inhibitor in the host, classified in class 424, subclass 93.2.
- VIII. Claims 27, 28 and 48, drawn to a method of treating a connective disorder in a mammalian host by introducing one or more DNA sequencing encoding one or more genes of interest into at least one target cell of the host, classified in class 514, subclass 44.

6. Inventions of the groups I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I-VII are drawn to a method of treatment by transplanting therapeutic proteins that have different sequence structure and function. For example, the function of BMP, IL-10, IL-1 receptor, TNF-alpha receptors, proteinase inhibitor etc. are distinct and therefore their effect on the metabolism of the host will be different. Therefore, the methods of groups I-VII are patentably distinct and will require separate searches in the patent and non-patentable literature and the searches will not be coextensive with each other. The invention of the group VIII is unrelated to that of the groups I-VII because the method of group VIII is an in vivo gene therapy method whereas the inventions of groups I-VIII are directed to an ex vivo method of therapy. The steps of the invention of group VIII are distinct from those of the groups I-VII and they cannot replace each other.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM SHUKLA
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632